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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,534	07/31/2003	Matthew M. Winkler	AMBI:065US	4029

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,534	WINKLER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-106* is/are pending in the application.

4a) Of the above claim(s) *74,75 and 102-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-73,76-101,105 and 106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/5/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of species an affinity domain and a nucleic acid ligand which reads on claims 64-73, 76-99, 105-106, in the reply filed on May 04, 2006 is acknowledged. Applicants' neither indicated whether the election is with traverse or without traverse and nor provided any arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status

2. Claims 64-73, 76-101, 105-106 read on elected species and are considered for examination claims 74-75, 102-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

Priority

3. This application filed on July 31, 2003 is a CON of PCT/US02/03169 filed on 1/30/2002 claims benefit of US provisional 60/265,692 60/265,693, 60/265,694, and 60/265,694 filed on 1/31/2001.

Information Disclosure Statement

4. The Information Disclosure Statement filed on November 05, 2003 has been entered and considered.

Specification

5. The following informalities were noted while reviewing the disclosure.

(i) the preliminary amendment filed on 7/31/2003 replaced beginning paragraphs on page 1 and 36 of the instant disclosure, which contains blank lines for concurrently filed U.S. application No.

(ii) claim 85 recites 'complementary acids' , should have been 'complementary nucleic acids'.

Correction required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64-73, 76-84, 86-101,105-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. (EP 0 870 842).

Kato et al. teach a method of claims 64, 105-106, for comparing one or more nucleic acid targets within two or more samples comprising:

(a) preparing a sample mixture by a process comprising obtaining at least a first sample and a second sample, each potentially having at least a first nucleic acid target and mixing the first and the second nucleic acid sample to create a mixture (see page 2, line 48-52, page 7, line 1-57, page 8, line 1-45, page 9, line 41-55, page 10, line 1-57, page 11, line 1-3);

(b) isolating at least a first target fraction of the sample mixture (see page 8, line 45-46, page 11, line 5-15);

(c) performing at least a first amplification reaction on the first target fraction, wherein the amplification reaction produces at least a first amplified nucleic acid if the first nucleic acid target is present, and at least a second amplified nucleic acid, if the first nucleic acid is present in the second sample (see page 8, line 46-57, page 9, line 1-9, page 11, line 17-33);

(d) differentiating the first and second amplified nucleic acids present in the first target fraction, if any (see page 9, line 10-20, page 12, line 11-23);

(e) comparing abundance of the first amplified nucleic acid target of said first sample to the abundance of the first nucleic acid target of the said second sample (see page 9, line 20-37, page 12, line 24-40)

With regard to claims 105-106, Kato et al. also teach preparing tagged first and second nucleic acid samples (See page 8, line 1-39, page 10, line 10-57).

With regard to claim 65, Kato et al. teach that the amplification reaction on the first target fraction is performed using a first target-specific primer (see page 4, line 26-30, page 8, line 6).

With regard to claim 66, Kato et al. teach that the method comprises performing a second amplification reaction using a second target specific primer (see page (page 11, line 41-57, page 12, line 1-10).

With regard to claim 67, 105-106, Kato et al. teach that the method comprises preparing tagged first and second nucleic acid samples each tag comprises a differentiation domain (restriction enzyme recognition domain), mixing tagged first and second samples to create a mixture and performing a first amplification reaction on a first target fraction (see page 7, line 30-57, page 8, line 1-57, page 9, line 1-57).

With regard to claims 68-73, 77, Kato et al. teach that the tags are appended between amplification domain and the target sequence and the method comprises plurality of samples and plurality of tags, wherein the tags are functional equivalent or identical to amplification domain (see page 2, line 25-36, page 10, line 1-57, indicating that the method comprises at least two samples and different adaptor tags having at least one restriction site, which reads on plurality of samples and tags).

With regard to claim 76, 88-92, Kato et al. teach that the differentiation domain comprises an affinity domain which are labeled (labeled adaptor has affinity to sterptavidin-coated para-magnetic beads) (see page 8, line 1-57, page 10, line 1-57).

With regard to claims 78-84, 86-87, Kato et al. teach that the first target fraction is isolated by binding a ligand (adaptor), which is a nucleic acid complementary to a segment of said target and said complementary nucleic acid is used to separate the first target from the plurality of the nucleic acid targets by binding it to a solid support (paramagnetic beads) (see page 8, line 1-57, page 10, line 1-57).

With regard to claims 93-96, Kato et al. teach that the affinity domain comprises a first detectable signal specific to the first target and a second detectable signal specific to the second target and results in distinguishable detectable signal (see page 12, line 14-35).

With regard to claims 97-98, Kato et al. teach that the differentiating comprises sequencing the amplified nucleic acids and the differentiation domain is a unique size domain (see page 12, line 11-40, page 2, line 35-36).

With regard to claim 99-101, Kato et al. teach that the tags comprise at least one additional domain comprising one or more restriction enzyme domains (see page 2, line 35-36, page 5, line 10-41).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (EP 0 870 842) in view of Wang (US 6, 004, 755).

Kato et al. teach a method of comparing one or more nucleic acid targets within two or more samples as discussed above in section 6.

Although Kato teaches the use of a solid support, Kato did not specifically teach that the solid support is an array comprising plurality of complementary nucleic acids bound to said array.

Wang teaches a method for quantitative gene expression analysis using a microarray, wherein the array comprises plurality of complementary probe sequences bound to it (see col. 1, line 66-67, col. 2, line 1-10).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of comparing one or more nucleic acid targets as taught by Kato et al. with a step of using an array as taught by Wang for the purpose of developing a sensitive high throughput assay format to compare the expression of plurality target nucleic acid. One skilled in the art would be motivated to combine the method as taught by Kato et al. in a manner taught by Wang by the inclusion of an array bound complementary nucleic acids because Wang explicitly taught the use of a microarray in screening gene expression of plurality of target sequences in a high throughput format and quantitating the genetic profile (see col. 1, line 6-32, line 66-67, col. 2, line 1-10). An ordinary artisan would have a reasonable expectation of success that inclusion of an array bound complementary sequences would result in a high throughput analysis of plurality of targets at a given time reducing the time to perform the method and use of reagents and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Non-Statutory Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-73, 76-99, 105-106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-116 of copending Application No. 10/632,539. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 64, 67, 105-106 is generic to all that is recited in claims 52, 102, 105, 108, 113, 115 of the co-pending patent application. That is, the claims 52, 102, 105, 108, 113, 115 of the co-pending application fall entirely within the scope of claim 62, 67, 105-106 or in other words, claim 64, 67, 105-106 are anticipated by the claims 52, 102, 105, 108, 113, 115 of the co-pending application. Specifically the method of steps (a)- (g) of the claims 52, 115, steps (a) –(h) of claims 105, 108, steps (a) –(e) of 113 are within the scope of the instant claims 64, 67, 105-106. Further, claims 65-66, 68-99 are generic to all that is recited in claims 53-101, 103-104, 106-107,

109-112, 114, 116 of the co-pending application. Thus the instant claims encompass the claims in the patent application and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method is obvious over the claims in the co-pending patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1637

Prabha Chunduru
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PATENT EXAMINER
7/7/06